IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ABBOTT GMBH & CO., KG, ABBOTT BIORESEARCH CENTER, INC., and ABBOTT BIOTECHNOLOGY LTD.,	)	C.A. No. 4:09-CV-11340 (FDS)
Plaintiffs,	)	JURY TRIAL DEMANDED
v.	)	**PUBLIC REDACTED VERSION**
CENTOCOR ORTHO BIOTECH, INC. and CENTOCOR BIOLOGICS, LLC.,	)	
Defendants.	)	

CENTOCOR'S REPLY IN SUPPORT OF ITS DAUBERT MOTION TO EXCLUDE TESTIMONY OF ABBOTT EXPERT JOAN ELLIS

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I. SUMMARY OF ARGUMENT IN REPLY

Abbott says Ms. Ellis' opinion on priority was *not* predicated solely on her analysis of the sufficiency of Centocor's evidence [redacted] that, instead, Ms. Ellis also considered the sufficiency of *Abbott's* evidence and concluded that Abbott had reduced its invention to practice before that date. But Ms. Ellis' testimony to the contrary is unequivocal:

[redacted]

Abbott says Ms. Ellis' opinion regarding the sufficiency of Centocor's evidence – based on her insistence that the Centocor inventors cannot have reduced the invention to practice without specifically appreciating that their antibody had the functional properties recited in each Abbott patent claim – was not predicated on an error of law. But Abbott fails to show that this squares with the pertinent Federal Circuit law. The cases it cites are not on point, and it does not even try to explain-away the Federal Circuit's directly applicable *DuPont* decision.

Finally, Abbott says Ms. Ellis, by reason of her education and experience, is qualified to testify about the patents' file histories and the patenting and interference processes generally. But, even if that were the case, such testimony is not the subject of Centocor's *Daubert* motion. This motion is directed to precluding Ms. Ellis' opinion on priority. And for all of the reasons presented in Centocor's opening memorandum, further explained below, exclusion of that unreliable opinion testimony is warranted.

II. MS. ELLIS' PRIORITY OPINION SHOULD BE EXCLUDED

A. Abbott Mischaracterizes the Bases for Ms. Ellis' Priority Opinion

Ms. Ellis' opinion that Centocor was not first to invent the antibodies of the patent claims could be based on only two things: (1) Centocor's evidence of a reduction to practice/invention date was somehow lacking, and/or (2) Abbott can prove a date reduction to practice/invention before any Centocor date. [redacted] But now Abbott suggests that Ms. Ellis' priority opinion should be permitted because it *also* turns on her analysis of Abbott's documentary evidence and "was based on the fact that Abbott's reduction to practice dates predated all the Centocor reduction to practice dates." (Abbott Opp. at 5). This is dead wrong.

[redacted] Abbott wrongly accuses Centocor of a "distorted reading" of Ms. Ellis' opinion, but the distortion is Abbott's suggestion that Ms. Ellis can opine that Centocor cannot prove prior invention because Abbott "might" be able to show reduction to practice based on certain evidence. No, as her report and deposition testimony make clear, her opinion that

Centocor cannot prove prior invention was based solely on her misguided conclusion that the Centocor inventors did not appreciate that their Stelara antibody had all of the properties recited in the Abbott claims – as reiterated below, a plain error of law.

B. Abbott Mischaracterizes the Law

Each of the patent claims asserted by Abbott recites a human antibody that binds to IL-12. Some of the claims add the requirement that the antibody have a particular affinity characterized by a K_d or K_{off} value, and some add the requirement that the antibody bind to the p40 subunit of the antigen. Stelara has been found to infringe several of the asserted patent claims, and Abbott contends that it infringes the remaining claims. [redacted]

Abbott contends, and Ms. Ellis offers the opinion, that this evidence of Centocor's isolation of an antibody encompassed by the Abbott patent claims is insufficient to prove an [redacted] reduction to practice of Abbott's claimed invention because Centocor did not prove that its inventors *knew* at the time that the Stelara antibody met the specific limitations of the claims. (Ex. 1, Ellis Rpt. at ¶¶87, 98; Abbott Opp. at 7). That is not the law.

What the law requires for reduction to practice is that an embodiment of the invention be constructed and *determined to work for its intended purpose*. *Mycogen Plant Science, Inc. v. Monsanto Co.*, 243 F.3d 1316, 1332 (Fed. Cir. 2001). In addition, an actual reduction to practice of a claimed invention requires "contemporaneous recognition and appreciation of the invention represented by the [asserted patent claims]." *Id*. at 1335 (citation omitted). However, the inventor need not "establish that he recognized the invention in the same terms as those recited in the [claims]" as "[t]he invention is not the language of the [claims] but the subject matter thereby

defined." *Silvestri v. Grant*, 496 F.2d 593, 599 (C.C.P.A. 1974); *Mycogen*, 243 F.3d at 1336 ("The reduction to practice test does not require *in haec verba* appreciation of each of the limitations of the [claims]."). Rather, the inventor must establish that he recognized and appreciated "a compound corresponding to the compound defined by the [claims]." *Silvestri*, 496 F.2d at 599.

The Federal Circuit decision most on point with the issue presented here is *E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co*., 849 F.2d 1430 (Fed. Cir. 1988), discussed at page 6 of Centocor's opening memorandum. Abbott's responsive brief is tellingly silent with respect to the *DuPont* case. The patent claim at issue in *DuPont*, as with the patent claims here, recited a composition of matter and included recitation of certain properties of that composition of matter:

> An interpolymer of ethylene and a higher olefinic hydrocarbon having 5 to 10 carbon atoms per molecule, said higher olefinic hydrocarbon having one terminal $-CH=CH_2$ per molecule and no other olefinic unsaturation, said interpolymer *being further characterized in that it has an X-ray crystallinity in the range of 40 to 70%, a melt index in the range of 0.3 to 20, a density in the range of 0.9 to 0.95 and said interpolymer being further characterized in that its density is not less than 0.93 unless the content of said higher olefinic hydrocarbon in the interpolymer is at least 3% by weight*.

849 F.2d at 1432 (emphasis added). The *DuPont* court held that a defendant seeking to prove anticipation of this patent claim by prior invention could do so by showing that its prior composition possessed the properties recited in the patent claim without proving awareness by the prior inventors that their composition possessed the properties. *Id*. at 1436. Similarly, here, Centocor can prove anticipation of the Abbott patent claims by showing that they had made an antibody that possessed the properties recited in Abbott's patent claims, and that they appreciated that the antibody would work for its intended purpose of neutralizing IL-12, without proving that the Centocor inventors were aware that Stelara had the specific properties recited in the claims.

The cases Abbott relies on are not to the contrary. Rather, they recognize the principle that, to establish a reduction to practice, the inventor must prove that he constructed an embodiment of the invention, understood that it would work for its intended purpose of the invention, and appreciated that he had the invention.

For example, *Teva Pharmaceutical Industries v. AstraZeneca Pharmaceuticals LP*, 661 F.3d 1378 (Fed. Cir. 2011) does not stand for the proposition, as suggested by Abbott and contrary to the *DuPont* holding, that the inventors must have appreciated that their prior invention possessed the features of the claims. The issue was whether AstraZeneca's CRESTOR product, if it met the limitations of Teva's patent claims, was invented first, so as to invalidate Teva's claims. The patent claims recited a stabilized pharmaceutical composition that included a "stabilizing effective amount" of an amido compound. It was not disputed that AstraZeneca's prior CRESTOR formulation was a stabilized composition and that it contained a stabilizing amount of an amido compound, but Teva had argued that AstraZeneca had not proven prior reduction to practice because its inventors had not appreciated that it was the amido compound contributing to the stability of the formulation. *Id*. at 1385. The district court rejected this argument, noting that a prior inventor "need not 'establish that he recognized the invention in the same terms as those recited in the [claims]'" and, rather, must only establish "that he recognized and appreciated 'a compound corresponding to the compound defined by the [claims].'" *Teva Pharm. Indus. v. AstraZeneca Pharms. LP*, 748 F. Supp. 2d 453, 466 (E.D. Pa. 2010) (quoting *Silvestri v. Grant*, 496 F.3d 593, 599 (C.C.P.A. 1974)). The Federal Circuit affirmed the district court's summary judgment of invalidity, stating the prior inventor need not "conceive of its invention using the same words as the patentee would later use to claim it." 661 F.3d at 1384.

Sometimes, it can only be determined that an embodiment *would* work for its intended purpose by determining (and being aware) that the embodiment has the properties recited in the patent claim. In those instances, proof of reduction to practice may require proof that the inventors were aware that the embodiment possessed the properties recited in the claims. These are the types of cases on which Abbott relies, but they do not stand for the broad proposition that a prior inventor must always show that he appreciated that his embodiment met all limitations of a patent claim.

In *Estee Lauder* (Abbott Opp. at 7-8), the court addressed the issue of an inventor's proof of reduction to practice by actually preparing a composition and knowing that it would work for its intended purpose. *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588 (Fed. Cir. 1997). The court held that, *when testing is required to show that a composition is useful*, the inventors must recognize the successful testing before there can be a reduction to practice. *Id.* at 593. *Estee Lauder* did *not* hold that the inventors must have appreciated that a composition possessed each of the limitations of a patent claim before they can claim a reduction to practice of that invention.

The same is true of the *Cooper v. Golfarb* case relied upon by Abbott (Abbott Opp. at 8). *Cooper v. Goldfarb*, 240 F.3d 1378 (Fed. Cir. 2001). The invention in the *Cooper* case was an artificial vascular prosthesis made from expanded polytetrafluoroethylene ("ePTFE"). *Id*. at 1381. At the time of the invention of the prosthesis, ePTFE was produced as tubes consisting of solid nodes of PTFE connected by thin PTFE fibrils. *Id.* The distance between the nodes is referred to as the fibril length, which the court expressly noted "is important to the suitability of the ePTFE material for use as a vascular graft." *Id.* In the *Cooper* case, one could not know whether the embodiment worked for its intended purpose (as a vascular graft) without having tested it or without knowing the fibril lengths. Cooper, the alleged prior inventor, had done

neither. *Id*. at 1384. Thus, the *Cooper* decision only addressed testing to show that an invention would work for its intended purpose, *i.e*., to establish utility. It did not hold that, to prove a prior reduction to practice of a claimed invention, inventors must always have appreciated that a compound possessed each limitation of a patent claim.

Abbott's reliance on *Silvestri v. Grant*, 496 F.2d 593 (C.C.P.A. 1974), is misplaced. (Abbott Opp. at 7). In *Silvestri*, the court addressed a priority dispute, in the context of an interference proceeding, over the inventorship of a new form of an antibiotic known as ampicillin. However, this case specifically addresses the appreciation required to establish a reduction to practice by a prior inventor. The *Silvestri* court expressly held that the law "does not require that [a prior inventor] establish that he recognized the invention in the same terms as those recited in the count. The invention is not the language of the count but the subject matter thereby defined. [The prior inventor] must establish that he recognized and appreciated [the] new form." *Id*. at 599.

This rule was later adopted by the Federal Circuit in *Mycogen*, 243 F.3d 1316, another case cited by Abbott that fails to support its position (Abbott Opp. at 7). In *Mycogen*, the court held that an actual reduction to practice requires construction of an embodiment and recognition of successful testing of that embodiment. *Id*. at 1335. The court focused on the "purpose of the invention" and found that "Monsanto appreciated that the invention worked for this purpose," and "upon learning of the test results . . . [the Monsanto scientists] immediately appreciated the significance of the results." *Id.* The court did not require extensive evidence of appreciation of certain "key limitations" of the invention, particularly in light of the evidence establishing that Monsanto made an invention that met all of the limitations of the claims, and that the resulting invention was successfully tested and appreciated to work for its intended purpose. *Id.* at 1337.

The issue in *Invitrogen Corp. v. Clontech Laboratories*, 429 F.3d 1052 (Fed. Cir. 2005) (Abbott Opp. at 7) was whether the alleged prior inventor *appreciated* his invention. The invention was a genetically modified enzyme, RT, that lacked RNase H activity, a property that made it useful for efficiently cloning DNA. *Id.* at 1058. Clontech claimed a prior invention based on work of Goff who, in 1984, had prepared 100 random mutations in the gene for RT, two of which produced enzymes that were later determined to lack RNase H activity. *Id.* at 1058-59. The testing of the RT mutants to determine whether they had RNase H activity was not done until 1987, after Invitrogen's invention date. *Id.* at 1066-67. The Court ruled that Goff had not set out to create RT lacking RNase H activity when he prepared his panel of mutant genes in 1984 and that the action "fit[ ] squarely within the unrecognized, accidental duplication cases." *Id*. at 1066.

Finally, Abbott's citation of *Dow Chemical Co. v. Astro-Valcour, Inc*., 267 F.3d 1334 (Fed. Cir. 2001) does not help its argument. (Abbott Opp. at 7). In *Dow*, the court held that that a prior inventor need not "establish that an inventor [is] the first to appreciate the patentability of the invention." *Id*. at 1341. *Dow* does not stand for the proposition that proof of reduction to practice of a patent claim requires proof that the inventor appreciated that his embodiment possessed every limitation of the patent claim.

The illogic of Ms. Ellis' legal argument that the Centocor inventors cannot have proven an invention date without appreciating that their Stelara antibodies possessed the exact properties recited in the Abbott patent claims is evidenced by Ms. Ellis' inability to respond to hypothetical questions during her deposition. [redacted]

[redacted]

[redacted] The Court can determine for itself whether Ms. Ellis' evasion was justified, but Centocor contends that she had to evade the questions because the only answer consistent with her opinion – an affirmative answer that it would be impossible to ever show earlier reduction to practice of such a claim – would have exposed the fallacy of her position.

C. The Admissibility of Other Testimony Ms. Ellis May Try to Present Is Not At Issue In This Motion

Abbott seems to want to change the subject by spending pages of its brief explaining why Ms. Ellis is allegedly qualified to testify to matters bearing upon the patenting and interference processes, the workings of the U.S. Patent and Trademark Office, the duties of a patent attorney, and the asserted patents' file histories (Abbott Opp. at 8-11). Whether Ms. Ellis is qualified to provide such testimony, whether it is within the scope of her expert report, and whether the Court would determine that such testimony would be helpful to the jury are issues for another day. (After conferring with Abbott, Centocor will be filing *in limine* motions, as needed.) But this entire section of Abbott's brief is off the point of Centocor's *Daubert* motion and in no way justifies allowing Ms. Ellis to offer priority opinions that are based on an error of law.

Nor does Abbott's attempt to explain why Ms. Ellis is qualified to testify about such things as the patenting process respond to the point made in Centocor's opening memorandum that she has no qualifications or expertise to offer an opinion on priority of invention. The jury does not need a patent attorney, even if she also has scientific training, to suggest to it how it should decide the evidence of priority. Ms. Ellis would be acting as an advocate, not an expert, and this should not be permitted.

III. CONCLUSION

Ms. Ellis' opinion on priority is based on an error of law and is unreliable. It should be excluded.

Dated: July 27, 2012 By: Dianne Elderkin

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing **Centocor's Reply in Support of its Daubert Motion To Exclude Testimony Of Abbott Expert Joan Ellis** was electronically mailed to counsel of record on July 27, 2012 through the Court's ECF system.

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